

Application Serial No. 10/007,812
Amendment dated December 20, 2007
Reply to Office Action of September 20, 2007

Amendment to the Drawings:

Replace the drawings filed with the application with the attached three sheets of drawings.

Attachment: Three sheets of replacement drawings.

REMARKS

The Examiner has rejected all of the pending claims as either fully disclosed by United States Patent No. 5,522,901 to Thomas et al. or obvious from Thomas et al. in combination with United States Patent No. 4,041,550 to Frazier, or United States Patent No. 6,280,476 to Metzger et al., or United States Patent No. 5,609,640 to Johnson.

By this amendment Applicant has amended claims 1 and 22 to require that the claimed patella replacement device have a shape conforming to a natural patella of a typical patient. Support for this addition can be found on page 6, lines 19-20, of the specification.

A. The Metzger reference is not prior art

The present application was filed on November 8, 2001. On January 7, 2004, Applicant filed a Declaration under Rule 131 in which he stated that he conceived the invention in 1989 and had an actual reduction to practice in the form of a prototype by March 15, 1990.

The '476 patent to Metzger et al. issued on August 28, 2001, from an application filed on May 5, 1999. That application claimed priority to an application filed on October 16, 1998. All of these dates are after Applicant's dates of conception and actual reduction to practice. Consequently, Metzger is not prior art under Sections 102(a) or 102(e). Since the Metzger patent issued less than three months before the present application was filed, this patent does not qualify as prior art under Section 102(b). Indeed, Metzger is not prior art under any paragraph of Section 102. Therefore, this patent cannot be a basis for rejecting any of the pending claims.

B. Thomas reference

The '901 Thomas patent discloses an implant for replacing a rear patella part. This implant is not suitable for replacing the entire natural patella of a patient. The abstract says that

"the implant can be attached in the natural patella part." As clearly shown in Figure 1, the implant has an attachment part 10 that fits into a cavity cut in the natural patella 1. The first paragraph in column 3 of the patent teaches that the "rear patella part is resected" (i.e. removed) and spherical depression 16 has been cut into the front natural patella part. The implant has an attachment part 10 made from metal which is placed into the spherical depression. Column 3, lines 6-7. Such attachment can be made using bone cement, but not using sutures. This part has an open-cell or open pore surface structure." Column 3, lines 8-9. The attachment part fits into a prosthesis part 2 made from plastic or ceramic material. Column 3, lines 8-9. The assembled structure does not have a shape that conforms to a patella of a typical patient. There is a projection that fits into a cavity cut in the natural patella that remains in the patient. No such projections are present in a natural patella. The assembled implant also does not have an annular ring that extends from the peripheral edge of the attachment surface of the attachment part. The structure 16 identified by the Examiner as a protruding annular ring fits into the prosthesis part 2. Consequently, this part 16 does not meet the requirements for the ring in amended claim 2. There is no gap between the attachment part and the prosthesis part. There are no coatings on the implant. There is no teaching or suggestion to use a bone growth material anywhere in the implant.

C. None of the claims as amended are anticipated by Thomas

The Examiner rejected claims 1, 5-8 and 12-14 as anticipated by Thomas. Claim 1 has been amended to require that the implant have a shape conforming to a natural patella. The device disclosed by Thomas does not have a shape conforming to a natural patella. Thomas's implant has a projection on one side that is inserted into a cavity cut in a natural patella.

Claims 5-7 depend from claim 1. Claim 8 is similar to claim 1 but requires a peripheral gap between the first and second member. Claims 12-14 depend from claim 8. Thomas does not teach or suggest a peripheral gap. Accordingly, none of these claims are anticipated by Thomas. Structure 16 in Thomas does not extend from the peripheral edge of the attachment part, but rather protrudes from the surface that mates with the prosthesis part.

D. The claims are patentable over the cited combination of Thomas with Metzger

The Examiner cited Thomas in combination with Metzger to reject claims 1, 5-8 and 12-13. Since Metzger is not prior art the rejection based upon Thomas in combination with Metzger is improper.

E. The claims are patentable over Thomas in view of Frazier

United States Patent No. 4,041,550 to Frazier discloses two embodiments of an artificial patella having a rigid wafer-like member 11 having several small circular openings. The first embodiment shown in Figures 1 and 2 is used when the natural patella has been removed. The rigid wafer-like member is attached to the patella tendon by sutures that pass through selected openings. A patella prosthesis is attached to the wafer-like member by bone cement. Column 2, lines 26-29. The patella prosthesis 14 is attached by a snap fit to a femoral prosthesis 17 that is secured to the femur by bone cement and pegs. Column 2, lines 32-52. A second embodiment shown in Figure 5 is used when a portion of the natural patella is present. This embodiment has short "pegs 19a on its [the wafer-like part] outer side which are adapted to extend into complementary opening formed in the adjacent surface of the remaining natural patella 20a." col. 3, lines 23-25. The wafer-like member is secured to the remaining natural patella "partly by means of short pegs 19a which are held by bone cement." col. 3, lines 30-33. This second

embodiment is similar to the implant disclosed by Thomas in that both implants have a projection that is inserted into a cavity cut in a natural patella. None of these components in Frazier's implant have a rounded fixation surface. The assembled structure cannot articulate against the femur or the femoral area of the patient. Articulation occurs at the snap fit connection. There is no annular ring or peripheral gap between the wafer-like member 11 and the patella prosthesis 14. There is also no teaching or suggestion of bone growth material on the artificial patella.

To establish a prima facie case of obviousness, three basic criteria must be met. "First, there must be some suggestion or motivation, in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." MPEP § 2142. "Second, there must be a reasonable expectation of success." *Id.* "Finally, the prior art reference (or references when combined) **must teach or suggest all the claimed limitations.**" *Id.* (emphasis added). "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." *Id.*

"The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." *Id.* To suggest or teach toward an invention, the "prior art must suggest the desirability of the claimed invention." MPEP § 2143.01. "**The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.**" *Id.* (emphasis added).

Further, any proposed change or modification of prior art must not change the principle of operation disclosed by the reference. *Id.* For example, a proposed modification of a prior art invention must not render the modified device unsatisfactory for its intended purpose. *Id.*

The Examiner has rejected claims 2-4, 9-11 and 15-21 as unpatentable over Thomas in view of Frazier. Claim 2 was amended to require that the ring encircle the rounded fixation surface. At page 5 of the Office action the Examiner asserts, "Frazier discloses a patellar implant and teaches providing a plurality of apertures about a periphery of the device in order to allow sutures to pass therethrough and retain a damaged patella in place (see, e.g., Figs. 2 and 4, col. 1 lines 5-8 and col. 2, lines 15-21)." Only Figures 4 and 5 show the implant being attached to remaining natural patella. The patent teaches at column 3 that the implant is attached to the remaining bone "by means of short pegs 19a which are held by bone cement." col. 3, lines 30-33. One skilled in the art reading Thomas in combination with Frazier would learn that one can attach an implant to remaining patella bone by forming a cavity in that remaining bone and providing a projection on the implant that fits into the cavity. One would also learn that one could use bone cement in that cavity. Thomas requires that there be at least some remaining bone for his implant. The second embodiment of Frazier also requires that there be some remaining patella to which the implant is attached by one or more projections. Thus, one skilled in the art reading Thomas and Frazier would be lead to an implant having one or more projections for insertion into one or more cavities cut in the remaining natural patella. To the extent that the combination of references teaches anything about implants for situations where no natural patella exists, that teaching is limited to the first embodiment of Frazier. Importantly, none of the implants taught by the combination of Thomas and Frazier have a shape conforming

to a natural patella. Therefore, claim 1 and the claims that depend from claim 1 are patentable over this combination.

F. The claims are patentable over Thomas in view of Johnson

The Examiner has rejected claims 22-26 as unpatentable over Thomas in view of Johnson. United States Patent No. 5,609,640 discloses a patella prosthesis having a mushroom shaped member with a head that is contoured to correspond to a human patella. The entire prosthesis, however, is not shaped to conform to a natural patella. Johnson teaches that hydroxyapatite coating may be applied to the implant. Like Thomas and Frazier, the implant disclosed by Johnson has a projection 2 from one surface. Claim 22 has been amended to require that the implant have a shape conforming at a natural patella. The implant disclosed by Johnson has no such shape. Taken together, none of the prior art references cited by the Examiner teach or suggest an implant for replacing a damaged patella in which the implant has a shape corresponding to a natural patella. Instead, the art teaches to have a flat surface which is sewn to the tendon or to provide one or more projections which are inserted into corresponding cavity or cavities cut in the remaining natural patella.

G. Objections to the drawings

Submitted herewith is a new set of drawings have better line quality. In Figure 8 the apertures are drawn to show that they all extend the same distance through the device. New Figure 10 showing the assembled implant illustrated in Figure 2 has been added. The specification was amended to identify this new figure. The peripheral gap is identified by reference number 40 in the specification. That reference number appears in Figure 10. The new drawings overcome the Examiner's objection.

H. Objections to the Specification

The Examiner objected to the term a ring in the specification saying it was inconsistent with the drawings. Applicant respectfully disagrees. A ring is defined as an area between concentric circles. When the patella implant is assembled, the structure identified as a ring has an exposed portion which consists of an area between to concentric circles. See Figures 3, 4 and 7 of the application.

It is well settled that a patent applicant can be his own lexicographer provided terms used are not inconsistent with the general understanding. Finally, Applicant notes that this same invention is the subject of United States Patent No. 6,146,423 to Cohen. Applicant has sworn behind this patent and sought to provoke an interference. The structure identified in the present application as a ring is also identified by Cohen as a ring. See Col. 3, line 3. For all of these reasons, Applicant submits that the objection to the use of the term ring is not well founded and should be withdrawn.

The Examiner also said that the specification of record has distorted text that is difficult to read. This apparently happened when the specification submitted by Applicant was scanned into an electronic format by the Office. To overcome the problem the Examiner has requested that another copy of the specification be submitted. A copy of the original specification as filed in this case is submitted herewith.

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CONCLUSION

For the foregoing reasons Applicant submits that the claims as amended are patentable over the cited references. Furthermore, the objections to the specification and drawings have been overcome. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lynn J. Alstadt", written over a horizontal line.

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